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JAN - 5 2007

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JAN - 5 2007

Richard E. Hill, Jr.
Center for Veterinary Biologics
510 South 17th Street
Suite 104
Ames, IA 50010

Dear Mr. Hill

The attached application for patent term extension of U.S. Patent No. 5,510,106 was filed on August 20, 2003, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, FEL-O-VAX® LvK/FIV vaccine, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Note the discussion at the top of page 3. FEL-O-VAX® FIV (apparently a different formulation of the vaccine) was previously approved and was the subject of an application for patent term extension for U.S. Patent 5,275,813, which was granted an extension for 5 years. We understand that the present formulation of FEL-O-VAX® LvK/FIV contains inactivated feline leukemia virus, inactivated subtype A FIV persistently infected cells, and inactivated subtype D FIV persistently infected cells, whereas the previously approved formulation contained inactivated subtype A and subtype D FIV whole virus.

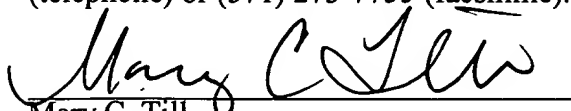
Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Please note that the Office has a new Mail Stop for Patent Term Extensions filed under 35 U.S.C. § 156:

Mail Stop Hatch-Waxman PTE
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Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

A handwritten signature in cursive script, appearing to read "Mary C. Till", is written over a horizontal line.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Kevin L. Bastian
Townsend & Townsend & Crew
Two Embarcadero Center, 8th Floor
San Francisco CA 94111-3834



IMPORTANT NEW INFORMATION FOR PTE FILERS!

In order for the Office to process applications for Patent Term Extension under 35 U.S.C. § 156 more efficiently, the mail stop for these applications has been changed. Effective November 21, 2006, please direct all applications for Patent Term Extension under 35 U.S.C. § 156 to:

MAIL STOP: HATCH-WAXMAN PTE

The Office published a Notice concerning the new mail stop on November, 21, 2006. See <http://www.uspto.gov/web/patents/patog/week47/OG/TOC.htm#ref20>. Future editions of the MPEP will be updated to reflect this change. Questions concerning applications for Patent Term Extension under 35 U.S.C. § 156 may be directed to Mary C. Till at (571) 272-7755 or Kathleen K. Fonda at (571) 272-7754.